UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

ELIZABETH A. RADER, *Plaintiff,* v. AMERICAN MEDICAL SYSTEMS, INC., *Defendants.*	)	MDL: 2325 Case No.: 2:12-cv-3503

COMPLAINT

Comes now Plaintiff Elizabeth A. Rader and files this Original Complaint against Defendant American Medical Systems, Inc. as follows:

PARTIES

1. Plaintiff Elizabeth A. Rader is a citizen of the State of Kentucky.

2. Defendant American Medical Systems, Inc. ("AMS") is a Delaware corporation with its corporate headquarters in Minnesota.

JURISDICTION AND VENUE

3. This is a lawsuit for personal injury damages in excess of $75,000.00. The parties are citizens of different states.

4. At all times material hereto, Defendant did business in the State of Kentucky. Additionally, Defendant had contacts and did business in West Virginia. This Court has diversity jurisdiction pursuant to 28 U.S.C § 1332.

5. Venue is proper pursuant to the Order on the Judicial Panel on Multidistrict Litigation and Pretrial Order #1, paragraph 2, dated February 29, 2012, entered by Honorable Judge Joseph R. Goodwin.

6. All conditions precedent to the maintenance of this action have occurred, have been performed, or have been waived.

FACTUAL ALLEGATIONS

7. AMS designs, manufactures, markets, packages, labels and sells medical devices, including the medical device known as the AMS Elevate and AMS Monarc (hereinafter "Products"), medical devices implanted to treat certain women like Plaintiff for pelvic organ prolapse and stress urinary incontinence.

8. Plaintiff Elizabeth A. Rader was implanted on or about December 30, 2010 in Kentucky with the Products designed, manufactured, marketed, packaged, labeled, sold, and placed in the stream of commerce by AMS. Due to defective design, defective manufacturing, defective marketing, and negligence by AMS, the Products have caused Plaintiff severe and permanent bodily injuries and significant mental and physical pain and suffering, and economic losses.

9. The Products and the surgical mesh used to manufacture the Products have numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences. These defects include, but are not limited to:

a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.

b. The mesh material harbors infections that adversely affect human tissues and patient health.

c. The Products and the mesh migrate from the location of their implantation, adversely affecting tissues and patient health.

d. The mesh material abrades tissues adversely affecting patient health.

e. The Products and the mesh regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.

f. Due to their various defects, the Products and the mesh regularly cause significant injury to patients such that the Products must be removed, resulting in additional surgery.

g. The Products and the mesh become embedded in human tissue over time such that if they need to be removed due to various defects, the removal causes damage to organs and tissues, adversely affecting patient health.

h. The Products are defective in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered for use in the female pelvis.

10. Because of their numerous defects, the Products creates an unreasonable risk of injury and other adverse health consequences for patients, including, but not necessarily limited to, vaginal erosion, infection, extrusion, perforation, chronic pain and/or abscess.

11. Prior to the time that the Products were implanted into Plaintiff, AMS was aware of numerous defects in the Products and the mesh, including, but not limited to, the defects and unreasonable risks identified above. Despite being aware of the numerous defects and

unreasonable risks in its Products, AMS manufactured, marketed, and distributed the Products with the intent that they would be implanted in patients. AMS was aware that implanting the Products in patients was likely to cause injury and harm to the patients into whom the Products were implanted. Alternatively, AMS failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Products into patients.

12. AMS made public statements in the form of written product descriptions, product labels, promotional materials and other materials that asserted that implanting the Products in patients was safe and would not cause harm to patients. These statements were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public would pay for the Products and that the Products would be implanted in patients. When AMS made these statements, AMS knew that the statements were inaccurate. Alternatively, when AMS made these statements AMS should have known the statements were inaccurate.

13. Representatives of AMS also made statements to numerous individuals, including medical professionals, that implanting the Products in patients was safe and would not cause harm to patients. When AMS representatives made these statements, AMS knew that the statements were inaccurate. Alternatively, when AMS representatives made these statements, AMS should have known the statements were inaccurate.

14. AMS knowingly and deliberately made material misrepresentations to the Federal Food and Drug Administration concerning the design, manufacture, safety, and efficacy of the Product.

15. Before Plaintiff suffered the injuries complained of herein, AMS was on notice of numerous bodily injuries caused by the Products, and based thereon, AMS knew or should have

known that the Products caused an unreasonably high rate of vaginal erosion, infection, extrusion, perforation, chronic pain and/or abscess in women implanted with the Products.

16. Even though AMS has known or should have known that the Products created a foreseeable, unreasonable risk of harm to those women into whom they were implanted, AMS continued to market the Products in the United States. Defendant has sold thousands of the Products in the United States alone.

17. Defendants have never provided adequate warning or information of the risks that the Products cause an unreasonably high rate of vaginal erosion, infection, extrusion, perforation, chronic pain and/or abscess to physicians who are implanted the Products, or to women implanted with the device.

COUNT I – STRICT LIABILITY – DEFECTIVE MANUFACTURE

18. Plaintiff hereby incorporates all of the allegations contained in the foregoing paragraphs of this Complaint in their entirety as if fully rewritten herein.

19. One or more of the defects in the Products are the result of improper or incorrect manufacturing processes that result in the Products as manufactured deviating from their intended design. The defects caused by manufacturing defect rendered the Products unreasonably dangerous to consumers and to Plaintiff. The defects in the Products implanted in Plaintiff existed from their manufacture; therefore the defects were present when they left the possession and control of AMS. As a direct and proximate result of the defective manufacture of the Products, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT II – STRICT LIABILITY – DEFECTIVE DESIGN

20. Plaintiff hereby incorporates all of the allegations contained in the foregoing paragraphs of this Complaint in their entirety as if fully rewritten herein.

21. The Products are unreasonably dangerous and dangerously defective as designed because as designed they have numerous defects that adversely affect patient health. The defects in the Products existed from their inception; therefore the defects were present when they left the possession and control of AMS. The foreseeable risks of harm posed by the design of the Products could have been reduced and/or avoided by the adoption of a reasonable alternative design by AMS, and the failure of AMS to adopt a safer alternative design rendered the Products unreasonably unsafe. As a direct and proximate result of the defective design of the Products, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT III – STRICT LIABILITY – MARKETING DEFECT

22. Plaintiff hereby incorporates all of the allegations contained in the foregoing paragraphs of this Complaint in their entirety as if fully rewritten herein.

23. The Products were defective by reason of failure of AMS to provide adequate warnings or instructions.

24. Defendants failed to provide such warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Products or to those women who had been implanted with the Products, concerning the following risks, of which Defendants had actual or constructive knowledge at the time the Products left Defendant's control:

a. the high failure rate of the Products;

b. the high rate of infections and abscesses caused by the Products;

c. the high rate of vaginal erosions and extrusions caused by the Products;

d. the high rate of chronic pain caused by the Products; and

e. the necessity to remove the Products from the patient's body in the event of the Products' failure, infections, abscesses, erosion, or extrusion.

25. After receiving notice of numerous bodily injuries resulting from the Products, AMS failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Products or those women who had been implanted with the Products that the Products were causing an unreasonably high rate of infections, abscesses, erosions and/or extrusions. Furthermore AMS failed to provide post-marketing or post-sale warnings or instructions concerning the necessity to remove the Products from the patient's body in the event of the product failure, infections, abscesses, erosion, or extrusion.

26. As a direct and proximate result of the inadequate warnings and instructs by AMS, both at the time of marketing and after the sale of the Products, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT IV – NEGLIGENCE

27. Plaintiff hereby incorporates all of the allegations contained in the foregoing paragraphs of this Complaint in their entirety as if fully rewritten herein.

28. AMS failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the Products and AMS negligently failed to provide adequate warnings and instructions to Plaintiff or to her physician regarding the Products.

29. As a direct and proximate result of the negligence of AMS, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT V – BREACH OF WARRANTY

30. Plaintiff hereby incorporates all of the allegations contained in the foregoing paragraphs of this Complaint in their entirety as if fully rewritten herein.

31. The Products implanted in Plaintiff failed to function as intended and as represented by AMS because they did not relieve the symptoms or otherwise alleviate the medical problems that they were intended to cure. Instead, the Products caused Plaintiff to suffer infection or inflammation, tissue abrasion, and other severe adverse health consequences. Accordingly, the Products were not fit for the ordinary purposes for which such goods are used and failed to conform to the affirmations or representations of AMS. Furthermore, AMS knew that the Products were to be used for the particular purposes for which they were used on Plaintiff and knew that the expertise of AMS was relied upon to furnish suitable goods. Because the Products failed to conform to representations and was not suitable for the purposes for which they were used, AMS has breached express warranties, the implied warranty of merchantability, and the warranty of fitness for a particular purpose. As a result of AMS's breach of warranty, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

VII. PUNITIVE DAMAGES

32. At the time AMS designed, manufactured, marketed, labeled, packaged, and sold the dangerous and defective Products and failed to adequately warn Plaintiff of the dangerous and defective nature of the Products and thereby caused Plaintiff's injuries, AMS knew, or in the exercise of the appropriate degree of care should have known, that its conduct created a high

degree of probability of injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiff, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

33. Plaintiff incorporates by reference all of the above paragraphs as if set forth in full herein.

34. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

35. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

36. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to the Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

37. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant is estopped from asserting a statute of limitations defense due to Defendant's fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the Products. As a result of

Defendant's fraudulent concealment, Plaintiff and Plaintiff's prescribing physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant.

38. The running of the statute of limitations in this cause may be tolled due to the pendency of a class action proceeding against one or more of the Defendant herein. Class Action tolling is proper where Plaintiff is a member of an asserted class and the claims asserted in the class action proceeding are the same as the claims asserted in this action.

39. Defendant is estopped from asserting a statute of limitations defense because Defendant fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection between the injury and Defendant's tortious conduct.

WHEREFORE, Plaintiff demands trial by jury, judgment against AMS for compensatory and punitive damages as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFF DEMANDS A TRIAL BY JURY

Date: July 20, 2012

/s/ Clayton A. Clark, Esq.
Clayton A. Clark, Esq.
Scott A. Love, Esq.
W. Michael Moreland, Esq.
Clark, Love & Hutson
440 Louisiana St., Ste. 1600
Houston, Texas 77002
Email: slove@triallawfirm.com
Email: mmoreland@triallawfirm.com
(713) 757-1400 Telephone
(713) 759-1217 Facsimile

Derek H. Potts, Esq.
Timothy L. Sifers, Esq.
Bret A. Clark, Esq.
The Potts Law Firm, LLP
Email: dpotts@potts-law.com
Email: tsifers@potts-law.com
Email: bclark@potts-law.com
908 Broadway, 3rd Floor
Kansas City, MO 64105
(816) 931-2230 Telephone
(816) 931-7030 Facsimile

Attorneys for Plaintiff